Section 5 510(k) Summary

(As required by 21 CFR 807.92(a))

SEP 17 2013

5.1 Submitter Information

· Company: Jinxinbao Electronic Co.,Ltd

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· Phone: 086-20-34938449

· Fax: 086-20-22865301

· Email: xhoucc@jxb-htb.net

· Contact: Jiacheng Guo, General Manager

· Date: November 15, 2012.

5.2 Device Information

· Trade/Proprietary Name: Electronic Blood Pressure Monitor for Upper Arm, Model BPA-002

· Common Name: Blood Pressure Monitor

· Classification: Device Class: 2

Review Panel: Cardiovascular

Name: Non-invasive Blood Pressure Measurement System

Regulation Number: 21 CFR 870.1130

Product Code: DXN

· Predicate Device: Fully Automatic Digital Blood Pressure Monitor, Model BP-1307, K120554

· Device Description:

BPA-002 Electronic Blood Pressure Monitor for Upper Arm uses an inflatable cuff which is wrapped around the patient's upper arm. The cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method and silicon integrate pressure sensor technology. The deflation rate is controlled by a preset mechanical valve at a constant rate. The

pressure of the cuff is completely released automatically at the end of measurement. At the same time, the measurements are displayed on the LCD display for 60 seconds.

There is a maximum pressure safety setting at 280mmHg. The device will not inflate the cuff higher than 280mmHg. It will display an irregular heartbeat symbol if an irregular heartbeat was detected during the measurement process. In addition, it has LCD backlight. After 60 seconds without operation, the blood pressure monitors turn off automatically.

· Intended Use:

BPA-002 Electronic Blood Pressure Monitor for Upper Arm is intended to measure systolic and diastolic blood pressures as well as the determination of heart rate by using the oscillometric method. All values can be read out in one LCD panel.

It is suitable for adult arm circumference and can be used by medical departments or for home use. However, it shouldn't be used by people who have severe arrhythmia.

5.3 Comparison of Required Technology Characteristics

Item	Subject Device	Predicate Device
Device Name	Electronic Blood Pressure Monitor for Upper Arm Model BPA-002	Fully Automatic Digital Blood Pressure Monitor Model BP-1307 (K120554)
Method of Measurement	Oscillometric	Oscillometric
Inflation Method	Automatic Internal Pump	Automatic Internal Pump
Deflation Method	Preset Mechanical Valve at a Constant Rate	Preset Mechanical Valve at a Constant Rate
Anatomical Site	Upper Arm	Upper Arm
Range of Measurement	Pressure: 0mmHg~280mmHg Pulse: 30~160 Beats/minute	Pressure: 0mmHg~300mmHg Pulse: 30~180 Beats/minute

Accuracy	Pressure: ±3mmHg Pulse: ≤5%	Pressure: ±3mmHg Pulse: ±5%
Operating Conditions	Temperature: 5℃~40℃ RH: 15%~85%	Temperature: 5℃~40℃ RH: <85%
Storage Conditions	Temperature: -10℃~60℃ RH: 15%~85%	Temperature: -10℃~55℃ RH: <95%
Power Supply	4 Batteries Size AA	4 Batteries Size AA
Display	Liquid Crystal Digital Display	Liquid Crystal Digital Display
Cuff Size	Arm Circumference: 22~30cm	Arm Circumference: 22~36cm
Unit Weight	About 430g (Without Batteries)	About 395g (Without Batteries)
Sets of Memory	99 Memories in three groups	120 Memories in two groups
Irregular Heart Beat Detection	Yes	Yes
Low Battery Indicator	Yes	Yes
Last 3 Results Average	Yes	Yes

Brief Summary:

The BPA-002 Electronic Blood Pressure Monitor for Upper Arm incorporates the same fundamental technology characteristics and design with the predicate device, such as measurement method, inflation and deflation method, anatomical site, power supply, display, irregular heart beat detection, low battery indicator and last 3 results average. Though they differ in the concrete parameters of measurement range, accuracy, cuff size and sets of memory, such differences will not influence the intended use of the subject device and will not lead to safety and effectiveness concerns.

5.4 Discussion of Tests Performed

· Clinical Tests:

Subject device BPA-002 is compliant to the SP10:2002/(R) 2008&ANSI/AAMI SP10:2002/A1:2003/(Manual, electronic or automated sphygmomanometers. All the relevant activities were performed by designate individual(s) and the results demonstrated that the predetermined acceptance criteria were fully met.

· Non-Clinical Tests

The subject device was tested to evaluate its safety and effectiveness according to the following standards:

a. Electrical Safety Test according to IEC 60601-1, Medical electrical equipment-Part 1: General requirements for basic safety and essential performance.

b. Electromagnetic Compatibility Test according to IEC 60601-1-2:2007, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance-Collateral standard: Electromagnetic compatibility-Requirements and tests.

c. Biocompatibility Test according to ISO 10993-5: 2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity and ISO 10993-10: 2010, Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization.

d. Performance Effectiveness Test according to SP10:2002/(R) 2008&ANSI/AAMI SP 10: 2002/A1: 2003/ (Manual, electronic or automated sphygmomanometers.

5.5 Conclusion:

First, the subject device BPA-002 Electronic Blood Pressure Monitor for Upper Arm enjoys the same intended use and similar technological characteristics with the predicate device. Besides, the performance safety and effectiveness of the subject device has been verified in accordance with the above FDA recognized standards, thus being considered to be as safe and effective as the predicate device.

In a word, it is reasonable for us to conclude that the subject device is substantially equivalent to the predicate device according to the above analysis.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

September 17, 2013

Jinxinbao Electronic Co., Ltd
c/o Ms. Helen Nan, General Manager
Wenzhou Cytech Information Service Co., Ltd.
RM-404, Bldg. 7, Jinhuichang Homeland, Liuhongqiao Rd.
Wenzhou City, 325000, Zhejiang Province.
CHINA

Re: K130232
Electronic Blood Pressure Monitor for Upper Arm, Model BPA-002
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: Undated
Received: August 7, 2013

Dear Ms. Nan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 Indications for Use Statement

510(k) Number (if known): ___K130232_____

Device Name: ___BPA-002 Electronic Blood Pressure Monitor for Upper Arm___

Indications for Use:

BPA-002 Electronic Blood Pressure Monitor for Upper Arm is intended to measure systolic and diastolic blood pressures as well as the determination of heart rate by using the oscillometric method. All values can be read out in one LCD panel.

It is suitable for adult arm circumference and can be used by medical departments or for home use. However, it shouldn't be used by people who have severe arrhythmia.

Prescription Use _____ AND/OR Over-The-Counter Use __×__

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.09.19 14:21:12 -04'00'

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